UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: May 17, 2011

Subject: Toxicology Data Needs Update: Bifenthrin Human Health Assessment Scoping Document in Support of Registration Review

PC Code: 128825
Decision No.: 448137
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcodes: D389066
Registration No.: NA
Regulatory Action: Registration Review
Case No.: NA
CAS No.: 82657-04-03
40 CFR: 180.287

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The scoping document for bifenthrin (May 25, 2010, D371583) listed the 90-day/28-day inhalation study (870.3465) and the immunotoxicity study (870.7800) as toxicology data needs. Upon further evaluation of the bifenthrin database, the Agency has determined that two additional toxicology studies [the acute inhalation study (870.1300) and a 90-day dermal study (870.3250)] are needed, and must also be included in the registration review data call-in. The 90-day dermal study (870.3250) will be used to evaluate dermal exposure of an intermediate duration, and the acute inhalation study (870.1300) will be used to define the acute toxicity category for this exposure route and for warning label signal words.

To summarize, the following are the updated toxicology data requirements for bifenthrin:

870.1300	Acute Inhalation Study
870.3250	90-day Dermal Study
870.3465	90-day/28-day Inhalation Study
870.7800	Immunotoxicity Study

The residue chemistry data requirements remain as listed in the May 25, 2010 Bifenthrin Scoping Document.

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Executive Summary

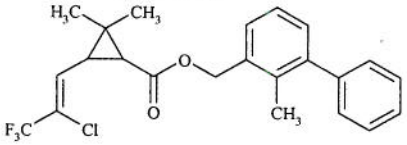
The Health Effects Division (HED) Bifenthrin Registration Review Team has evaluated the status of the human health assessments for the insecticide bifenthrin to determine the scope of work necessary to support Registration Review. The most recent risk assessment for bifenthrin

was completed in May 2008 for crop subgroup 13B and crop subgroup 4B. There is a pending new use under PRIA for forage grass and hay that may be included later in the registration review process. The toxicology database is incomplete with a data gap for immunotoxic effects (a new requirement for Part 158) and an outstanding 90-day inhalation study. The total uncertainty factor is currently 100X (1X FQPA Safety Factor, and 10X for inter-species variation and 10X for intra-species variation). However, the FQPA factor will be re-evaluated for bifenthrin following a final determination of the potential for increased susceptibility of infants and children to pyrethroid pesticides based on the results of all available data.

No exposure data have been requested for the registration of residential or occupational uses of bifenthrin. Further, no additional data gaps were identified in the residential and occupational exposure assessments during the registration review scoping process.

The Agency received a new use petition for bifenthrin in February 2002 for use in food handling establishments, as well as on a number of agricultural commodities, including almond hulls, tree nuts crops, leaf petioles subgroup 4B, tomatoes, spinach and starfruit. The residue chemistry review for this petition identified some deficiencies in the bifenthrin residue chemistry database (D283796, J. Liccione, 04-DEC-2002). To date, crop field trials for the following Raw Agricultural Commodities (RACs) have not been received: herb subgroup19A, artichoke, caneberry subgroup, hops, cotton gin byproducts, and grapes. Submission of these studies is still required. An updated dietary exposure assessment reflecting the current percent of crop treated (PCT), residue levels from recent PDP reports, and changes in the dietary burden is recommended when new crop field trial data or request for a new use is received. In addition, the following changes to the 40 CFR § 180.442 are recommended: (1) the tolerances for grapes and almond hulls should be increased and (2) the tolerance expression should be revised according to HED guidelines.

1.0 Introduction



Bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate) is a non-systemic insecticide/miticide in the class of synthetic pyrethroids. It is registered for uses on a variety of crops for the control of insect pests, including species in the orders Coleoptera (beetles), Lepidoptera (butterflies and moths), Homoptera (aphids, scales and mealybugs, leaf hoppers, whiteflies), Hemiptera (true bugs), and several species of mites. It is also registered for outdoor/indoor residential and indoor pet uses. End-use products are formulated as ready-to-use-sprays (RTU), emulsified concentrate (EC), wettable powders (WP), granular (G), flowable concentrate (FIC), and pelletized tablets. A wide range of application methods may be used including aerial, ground boom, air blast, belly grinder, push-type spreader, low/high pressure handwand, paint roller, and foggers, etc. The number of applications per season varies depending upon crop/site, pest, and rate of application. Use of the higher rates of application reduces the total number of applications that may be applied per season.

Current tolerances (ranging from 0.05 to 10 ppm) are established in 40 CFR §180.442 for residues of bifenthrin in/on various plant and livestock commodities. Time-limited tolerances for orchard grass and sweet potato roots (0.05 ppm) have been established in conjunction with Section 18 emergency exemptions [40 CFR §180.442(2b)]. A tolerance of 0.05 ppm is established for residues of bifenthrin in food and feeds as a result of uses in food/feed handling establishments [40 CFR §180.442(2)].

Human-heath risk assessments were completed on 12/4/2002, 4/6/06, and 7/25/07 and 5/14/08. The TRED and risk assessments examined all registered and previously pending uses of bifenthrin.

2.0 Hazard Identification/Toxicology

Bifenthrin is a neurotoxic insecticide acting through direct contact and ingestion, having a slight repellent effect. The primary biological effects of bifenthrin and other pyrethroids on insects and vertebrates are inhibition of the voltage-gated calcium channels coupled with a stimulatory effect on the voltage-gated sodium channels. All pyrethroids act as axonic poisons, affecting both the peripheral and central nervous systems, and share similar modes of action. Pyrethroids, including bifenthrin, stimulate repetitive action in the nervous system by binding to voltage-gated sodium channels, prolonging the sodium ion permeability during the excitatory phase of the action potential. This action leads to spontaneous de-polarizations, augmented neurotransmitter secretion rate and neuromuscular block, which ultimately results in paralysis of the insect.

Bifenthrin has a moderate order of acute toxicity via the oral route (Category II) and a low order of acute toxicity via the dermal route (Category III) of exposure. There are no acute inhalation studies on bifenthrin technical; however, acceptable studies on the end-use products are available. Bifenthrin has a low vapor pressure. It is neither an eye nor skin irritant, nor is it a dermal sensitizer.

Bifenthrin produces characteristic pyrethroid neurotoxicity. Tremors have been observed in developmental toxicity studies in the rat and rabbit, a 2-generation rat reproduction toxicity study, subchronic toxicity studies in the rat and dog, acute and sub-chronic neurotoxicity rat studies, a 21-day toxicity dermal rat study, chronic oral toxicity studies in the rat and dog, and oncogenicity studies in the rat and mouse. The sub-chronic and chronic oral toxicity studies in dogs and rats demonstrate neurotoxicological responses of similar magnitude. Staggered gait and exaggerated hindlimb flexion were noted in a 21-day dermal toxicity study in the rat. The neurotoxicity of bifenthrin has been supported by the results of acute and subchronic neurotoxicity studies in the rat. FOB findings were observed in these neurotoxicity studies. FOB findings consisted of tremors, abnormal posture, splayed hindlimbs, staggered gait, altered activity, altered landing foot-splay, twitching, uncoordinated movement/ataxia, and convulsions.

Bifenthrin is neither a developmental nor a reproductive toxicant. Bifenthrin has been evaluated for potential developmental effects in the rat (following gavage or dietary administration) and in the rabbit (gavage administration). Maternal toxicity included neurological effects (tremors in rats and rabbits; head and forelimb twitching in rabbits). There were no developmental effects of biological significance in either species.

The potential reproductive toxicity of bifenthrin was examined in a two-generation reproduction study in the rat. Tremors were noted only in females of both generations with one parental generation rat observed to have clonic convulsions. Administration of bifenthrin did not result in reproductive or offspring toxicity.

Bifenthrin was negative in most tests for mutagenicity. It was marginally mutagenic with and without S9 activation in the mouse lymphoma forward gene mutation assay. This finding has not been confirmed in a repeat test. There is also inconclusive, but presumptive, evidence that bifenthrin was mutagenic in the S9-activated phase of the Chinese Hamster Ovary Cell (CHO) gene mutation assay, however, this study was classified as unacceptable.

There was no conclusive evidence of carcinogenic potential of bifenthrin in the rat. A mouse oncogenicity study provided some evidence for carcinogenic potential in this species. In the mouse oncogenicity study, high-dose (81.3 mg/kg/day) males showed a highly significant increased incidence of urinary bladder tumors. Other findings in the mouse study included a dose-related trend of increased combined incidences of adenoma and adenocarcinoma of the liver (males only), and increased incidences of bronchioalveolar adenomas and adenocarcinomas of the lung in females at some, but not all dose levels relative to their controls. HED's Carcinogenicity Peer Review Committee (CPRC) has characterized bifenthrin as Category C (possible human carcinogen) primarily on the basis of a mouse study. The Cancer Assessment Review Committee (CARC) (1992) recommended that for the purpose of risk characterization, the reference dose (RfD) approach should be used for quantification of human cancer risk. The chronic exposure analysis revealed <100% RfD, and it is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. The decision was based in part on the statistically significant increased trend for hemangiopericytomas in the urinary bladders' of Swiss Webster mice. The incidence of these lesions was double at the highest dose tested (HDT; 600 ppm) as compared to controls. The male mice also had significant dose-related trends with respect to hepatocellular carcinomas and combined hepatocellular adenomas and carcinomas, and increased incidences of bronchioalveolar adenomas and adenocarcinomas of the lung in females at 50, 200 and 600 ppm (but not 500 ppm) relative to their controls. No compound related tumors were noted in rats. The mutagenicity evidence presents low concern for bifenthrin.

Several dermal absorption studies on bifenthrin are available; each study was considered acceptable for regulatory purposes when taken in conjunction with the other studies. The Hazard Identification and Review Committee (HIARC) recommended a dermal absorption rate of 25% based on the weight-of the-evidence available for structurally related pyrethroids.

A DNT study on bifenthrin was conducted in rats. In this study maternal and offspring toxicity was observed at the same dose levels. The maternal toxicity was primarily manifested as tremors, clonic convulsions, and increased grooming counts. The offspring toxicity was manifested as increased grooming counts. This study does not show any evidence of increased susceptibility of offspring following exposure to bifenthrin. However, based on the Agency's review of existing pyrethroid data, EPA has come to the conclusion that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. The Agency is investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms.

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, and or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Bifenthrin is among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. The Agency will review the EDSP Tier 1 data and any "other scientifically relevant information" submitted in response to test orders. Based on this review the Agency will determine the need for additional testing. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

The summary of endpoints and toxicological doses for bifenthrin are listed in Table 1.

Table 1 Summary of Toxicological Doses and Endpoints for Bifenthrin.

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary-general population, including infants and children	NOAEL = 32.8 mg/kg UF = 100 Acute RfD = 0.33 mg/kg/day	FQPA SF = 1X aPAD = acute RfD / FQPA SF = 0.33 mg/kg/day	Acute neurotoxicity study in rats. LOAEL = 70.3 mg/kg/day based on observations of mortality (females only), clinical and FOB findings and differences in motor activity.
Chronic Dietary-general Population, including infants and	NOAEL = 1.3 mg/kg/day UF = 100 Chronic RfD = 0.013 mg/kg/day	FQPA SF = 1X cPAD = cRfD / FQPA SF = 0.013 mg/kg/day	1-year oral toxicity in dogs. LOAEL = 2.7 mg/kg/day based on observations of increased incidence of tremors in both sexes.

Table 1 Summary of Toxicological Doses and Endpoints for Bifenthrin.			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**FQPA SF and LOC for Risk Assessment**	**Study and Toxicological Effects**
children			
Short-Term (1-30 days) Incidental Oral	NOAEL= 2.21 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X	90-day oral toxicity study in dogs. LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Intermediate-Term (1-6 months) Incidental Oral	NOAEL= 2.21 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X	90-day oral toxicity study in dogs. LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Short-Term (1-30 days) Dermal	Dermal NOAEL = 47 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X Occupational MOE = 100	21-day dermal study in rats. LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb reflex).
Intermediate-Term (1-6 months) Dermal	Dermal NOAEL = 47 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X Occupational MOE = 100	21-day dermal study in rats. LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb reflex).
Long-Term (>6 months) Dermal	Dermal NOAEL = 47 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X Occupational MOE = 100	21-day dermal study in rats. LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb reflex).
Short-Term (1-30 days) Inhalation	NOAEL= 2.21 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X Occupational MOE = 100	90-day oral toxicity study in dogs. LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.

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Exposure Scenario	**Dose Used in Risk Assessment, UF**	**FQPA SF and LOC for Risk Assessment**	**Study and Toxicological Effects**
Intermediate-Term (1-6 months) Inhalation	NOAEL= 2.21 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X Occupational MOE = 100	90-day oral toxicity study in dogs. LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Long-Term (>6 months) Inhalation	NOAEL= 1.3 mg/kg/day UF = 100 MOE= 100	Residential MOE = 100 FQPA SF = 1X Occupational MOE = 100	1-year oral toxicity in dogs. LOAEL = 2.7 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Cancer (oral, dermal, inhalation)	**Classification: Category C** (possible human carcinogen). No Q_1* has been derived. The RfD approach recommended for cancer assessment.		

UF = uncertainty factor, FQPA SF = FQPA Safety Factor, NOAEL = no–observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, RfD = reference dose (a = acute, c = chronic), PAD = population-adjusted dose, MOE = margin of exposure, LOC = level of concern, N/A = Not Applicable.

3.0 Dietary Exposure

Highly-refined acute and chronic dietary exposure assessments were conducted 02-APR-2008 with DEEM™ software using Pesticide Data Program (PDP) monitoring data, field trial data, processing factor data, and percent of crop treated (PCT) where applicable. This was the most recent dietary risk assessment performed as part of the new use petition for bifenthrin on bushberries subgroup 13B and leaf petioles subgroup 4B (D350901, W. Wassell, 02-APR-2008). The acute and chronic dietary risk assessments indicated that for all registered and pending uses the risk estimates were below HED's level of concern (<100% aPAD and < 100% cPAD) for the general population and all population subgroups. For the acute dietary risk assessment, the highest exposed population subgroup at the 99.9th exposure percentile were infants (<1 year old) with an aPAD of 25%. On the other hand, the chronic dietary risk assessment indicated that the highest exposed population subgroup were children (3-5 years old) at 55% of the cPAD.

DEEM default processing factors, and 100 PCT assumptions were used for several RACs. For other RACs, the PCT provided by the Biological and Economic Analysis Division (BEAD) was used for the exposure assessment. The maximum PCT was used for the acute assessment while the average PCT was used for the chronic assessment. As of October 19, 2009, the screening level estimates of agricultural uses of bifenthrin shows changes in the PCT for the following RACs (Bifenthrin SLUA report, 19-OCT-2009): almonds, artichokes, green beans, blackberries, cabbage, caneberries, cantaloupes, cauliflower, corn, cucumbers, grapes, honeydew, lettuce, pears, pumpkins, sweet corn, tomatoes and watermelons. In order to take into account current

trends in agricultural practices a reevaluation of the dietary risk assessment with the updated PCT values is recommended as part of the next new use proposed or when new field trial data are available. Moreover, for the RACs used for feedstuff, changes in PCT and in the percent of livestock diet should be considered and evaluated to determine if the dietary burden has changed significantly. In addition, the dietary burden shall be evaluated when the residues observed in the crop field trials with cotton gin byproducts are available.

USDA PDP monitoring data, 2002 FDA monitoring data and field trial data were used in the April 2, 2008 dietary assessment. Data from the 1998, 1999, 2000, 2001, 2002, 2003, 2004 and/or 2005 PDP reports were used for several RACs. New bifenthrin monitoring data are provided in the 2006-2007 PDP reports. The RACs with new data included in the 2006 and 2007 PDP reports are: broccoli, cauliflower, eggplant, grapefruit, orange juice, sweet peas, tomatoes, watermelon and winter squash. For some RACs, the number of samples analyzed, the number of detects and the range of residue values observed increased. Therefore, the use of the new PDP data in the next dietary exposure assessment should be considered.

The last Drinking Water Assessment (DWA) of bifenthrin was performed for new uses on the Leaf Petioles Subgroup 4B and Bushberries Subgroup 13B (D340933, J. Meléndez, 05-MAR-2008). This was the last new use for which bifenthrin was registered. A Tier 1 approach was used to estimate the surface and ground water concentrations. The Estimated Drinking Water Concentration (EDWC) for surface water was 0.0140 ppb, and the EDWC for ground water was 0.00300 ppb. Currently, there is no need for a new DWA.

4.0 Residue Chemistry

The nature of the residue in plants and livestock is adequately understood based on metabolism studies on corn, cotton, and apple, and goat and poultry, respectively. The Health Effects Division (HED) Metabolism Committee established that the residue of concern in plant and livestock commodities is Bifenthrin (Memo, M. Flood, 23-JUL-1993). Therefore, the parent compound [(2-methyl[1,1-biphenyl]3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylate] would be the relevant residue of concern to be established for the tolerance enforcement and risk assessment of crops.

In the 2002 residue chemistry review of the human health risk assessment for a new use petition, the Agency identified some deficiencies in the of bifenthrin residue chemistry database (D283808, S. Levy, 21-AUG-2002). Subsequently some issues were resolved by the petitioner (D286230, S. Levy, 17-OCT-2002). Also, other issues were resolved in the most recent risk assessment made to support new uses for bifenthrin in 2008 (342661, W. Wassell, 01-APR-2008) and with the revalidation of method P-1031 (D287669, J. Tyler, 11-FEB-2003). The following paragraphs discuss several deficiencies that remain outstanding from the 2002 residue chemistry review.

For grapes, three additional crop field trials (with the specified use pattern) were requested to fulfill geographic representation requirements, two in Region 10 and one in Region 11. These field trial data remain outstanding. A conditional registration with a tolerance of 0.60 ppm was recommended by HED because residue levels between 0.05 ppm and 0.56 ppm were observed in field trials conducted in California (D284223, S. Levy, 15-AUG-2002). Currently, the tolerance

for grapes established in the 40 CFR § 180.442 is 0.20 ppm. As part of the registration review, HED recommends to change the tolerance for grapes to 0.60 ppm.

For the tree nut group 14, field trial data with the Emulsifiable Concentrate (EC) formulation was requested (D283808, S. Levy, 21-AUG-2002). These data are no longer needed; it was submitted in a bridging study between the EC and 10% WP formulation. A tolerance of 0.05 ppm was recommended for almond nutmeat (D355743, P. Savoia, 10-DEC-2008). However, for the residues in/on almond hulls an increase in the tolerance from 2.0 ppm to 6.0 ppm was recommended based in the bifenthrin levels (0.96-5.96 ppm) found on the commodities treated with both formulations. Currently, the tolerance for almond hulls included in 40 CFR § 180.442 is 2.0 ppm. An update of the almond hulls tolerance specified in the CFR to 6.0 ppm is recommended as part of the current review. Almond hulls are used as a livestock feedstuff for dairy cattle. The dietary burden was recalculated with the 6.0 ppm tolerance and, based on the result, HED concluded that the established bifenthrin livestock tolerances would remain appropriate (D355743, P. Savoia, 10-DEC-2008). In addition, a revised version of method P-2763 for tolerance enforcement in walnuts was requested.

Agency has identified the need for the following crop field trials (D283808, S. Levy, 21-AUG-2002): (1) for container-grown herbs (subgroup 19A) reflecting the amended use (at the proposed pre-shipment interval) the submission of data was expected to occur in 2005, (2) for artichoke, the caneberry subgroup, and hops with the EC formulation (currently, the 25% EC formulation registered to be used on these commodities) and (3) for cotton gin byproducts.

On May 27, 2009, HED established interim guidance on writing tolerance expressions for enforcement purposes. In order to add clarity to the language used to establish the coverage of the tolerance expression and measurement of the level of the residue in the RACs the text in the 40 CFR § 180.442 should read: "(a) General. (1) Tolerances are established for residues of bifenthrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only bifenthrin ((2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate)".

Commodity	Parts per million
Almond, hulls	6.0*
Grapes	0.60*
See Attachment 2 for a full list of commodities.	

*These tolerances should be updated based on residue levels observed in field trials.

5.0 Residential Exposure

Residential exposure to bifenthrin is anticipated for individuals (adults) who apply bifenthrin-containing products and from post-application exposure in residential areas previously treated with the chemical. Multiple exposure assessments of bifenthrin residential uses have been conducted by the Agency. An assessment of exposure/risk from all residential uses registered was performed in an October 25, 2002 document, "Bifenthrin: Revised Residential Exposure

Assessment and Recommendations for the Tolerance Reassessment Eligibility Decision (TRED) Document (S. Weiss, D286358)." Since the 2002 risk assessment, the Agency has conducted an assessment of the following additional residential products: an indoor bifenthrin dust use, "Bifenthrin - Review "Discussion of Human Health Risk Assessment Assumptions for Bifenthrin Dust, MGK® F-2862 (M. Dow, D335827)", an indoor fogger, "Bifenthrin - Assessment of Exposures and Risks to Toddlers from the Proposed Use of Bengal Bi-Fogger 3 (M. Dow, D330481)"

Residential uses of bifenthrin are many and vary widely. HED used the Biological and Economics Analysis Division (BEAD) Label Data System to identify all residential uses of bifenthrin. The chemical is used in indoor residential/household premises in the form of crack and crevice sprays, as a paint additive, dust, and termite treatment. Outdoor residential uses of bifenthrin include broadcast and spot treatments to residential lawns/turf, golf course turf and outdoor premises (fencerows/hedgerows, paths/patios) by means of liquid spray and granular products, ornamental (turf, shrubs, vines, trees, ground cover), greenhouse plants, and automobiles/recreational vehicles. End use residential formulations of bifenthrin include emulsified concentrates, flowable concentrates, granulars, ready to use (RTU), and wettable powders. The 2002 risk assessment assessed residential exposure/risk from all uses of bifenthrin using maximum application rates for all formulations. The following exposure scenarios and maximum application rates or percent spray applied were assessed:

Exposure Scenario	Max. Application Rate/ % Spray
Low Pressure Handwand Application	0.06% Spray
Backpack Sprayer Application	0.06% Spray
Hose-end Spray Application	0.2 lb ai/day
Paintbrush Application	0.06% Spray
Belly Grinder Application	0.2 lb ai/acre
Push-type Spreader Application	0.2 lb ai/acre
Applying Granulars with Bare Hands	0.2 lb ai/acre
RTU Spray Bottle Application	0.05% Spray

In the 2002 risk assessment, the Agency departed from the default 10x safety factor to use instead a 3x factor to address the deficiencies in the database of bifenthrin. Therefore, the level of concern (LOC) for residential populations assessed in the 2002 risk assessment was a margin of exposure (MOE) ≥ 300 (i.e., 10x for interspecies extrapolation, 10x for intraspecies variability and an additional 3x for database deficiencies). The risk assessment estimated short- and intermediate-term handler exposure/risk. MOEs estimated for the dermal and inhalation routes were ≥ 300, and therefore, not of concern to the Agency (dermal MOEs ranged from 300 to 270,000; inhalation dermal MOEs ranged from 23,000 to 2,100,00; dermal and inhalation total MOEs ranged from 300 to 240,000). Post-application exposure/risk to previously treated residential areas was also assessed. The assessment of exposure/risk to adults (dermal only) and toddlers (dermal and oral) was conducted using maximum product application rates and considered the following exposure scenarios:

- Oral Exposure to Toddlers from Hand-to-Mouth Activity on Treated Turf
- Oral Exposure to Toddlers from Mouthing Treated Turf

- Oral Exposure to Toddlers from Incidental Soil Ingestion
- Oral Exposure to Toddlers from Incidental Ingestion of Granules
- Oral Exposure to Toddlers from Hand-to-Mouth Activity on Treated Indoor Hard Surfaces
- Oral Exposure to Toddlers from Hand-to-Mouth Activity on Treated Indoor Carpet
- Dermal Exposure to Adults and Toddlers from Treated Turfgrass

Short- and intermediate-term risks estimated by the 2002 risk assessment for post-application exposure from outdoor and indoor uses are not of concern to the Agency (oral MOEs ranged from 740 to 220,000; dermal MOEs ranged from 1,400 to 66,000).

Since the 2002 risk assessment, HED conducted an exposure assessment of a new use petition for an indoor bifenthrin dust product. The residential applicator and post-application assessment for the product resulted in a risk estimate which is not of concern to the Agency (i.e., an MOE $\geq$ 300).

6.0 Residential Handler and Post-application

All of the residential exposure scenarios for registered uses of bifenthrin have been assessed adequately. A granular product was identified that is applied at a rate of 0.4 lb ai/A. An exposure/risk assessment for the granular formulation at this rate cannot be identified. The potential exists for residential exposure to the granular product from playing on treated golf course turf, treating or tending to ornamental plants and turf, as well as exposure from the treatment and activities on recreational areas and lawns. Based on a comparison of previously assessed exposure scenarios for the registered granular rate, 0.2 lb ai/A, and the higher 0.4 lb ai/A rate, the latter would not result in a risk of concern to the Agency. An assessment of the granular product at the increased rate should be performed under registration review to capture the increase.

An updated residential assessment may be required under registration review based upon revisions to HED's Residential SOPs which was reviewed by the Scientific Advisory Panel (SAP) in October 2009. An updated assessment may also be required if new data are identified which impact exposure estimates, new points of departure, a revised FQPA SF, or revisions to exposure policies and procedures are made. Furthermore, based upon the final determination for bifenthrin uncertainty factors, the residential assessment of bifenthrin should be reviewed to ensure that exposure/risk estimates are health protective. No additional data gaps were identified in the residential exposure assessment during the registration review scoping process.

7.0 Aggregate Risk Assessment

In accordance with FQPA, HED considers and aggregates pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from dietary and residential sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL), or the risks themselves can be aggregated. When aggregating exposures and risks form various sources, HED considers both the route and duration of exposure.

Currently registered uses of bifenthrin include agricultural, as well as residential use sites. The most recent assessment of bifenthrin aggregate risk was conducted in the document, "Bifenthrin: Revised Human Health Assessment for a Section 3 Registration Request for Application of Bifenthrin and Establishment of Tolerances for Residues in/on Bushberries (Crop Subgroup 13B), Juneberry, Lingonberry, Salal, Aronia Berry, Lowbrush Blueberry, Buffalo Currant, Chilean Guava, European Barberry, Higbush Cranberry, Honeysuckle, Jostaberry, Native Currant, Sea Buckthorn, and Leaf Petioles (Crop Subgroup 4B) (W. Wassel, D352419, 5/14/2008)." This document considered the contributions from dietary pathways of food and drinking water to conduct the aggregate assessments. Short- and intermediate-term aggregate risks were assessed and determined not to be of concern to the Agency. Acute and chronic aggregate exposure/risks that incorporate residential uses were not assessed for bifenthrin since no residential exposures are anticipated for these durations of exposure (i.e., acute and chronic aggregate risks were assessed for food + drinking water only).

HED determined that adults could be exposed to bifenthrin through the residential application of the chemical via dermal and inhalation routes and through post-application exposure via dermal contact with treated turf. Children may be exposed following residential application of bifenthrin via dermal contact with treated turf and incidental oral exposure from mouthing hands exposed to treated turf. While a child could potentially ingest granules from treated turf, this exposure scenario is considered to be an episodic, or single occurrence, and likely not to be repeated. Therefore, this scenario was not aggregated with dietary exposure estimates. Results of the short- and intermediate-term aggregate assessment of bifenthrin were not of concern to the Agency (i.e., an MOE $\geq$ 100) for all populations considered. It is important to note that these estimates of adult and toddler risk are based upon residential exposures estimated from treatment with a granular product at a maximum application rate of 0.2 lb ai/A. It has since been determined that the granular application rate has been increased to 0.4 lb ai/A and, likewise, will impact these risk estimates. The worst case assessment of aggregate risk assessed in the 2008 document was the aggregation of dietary, residential and dermal risks for children 3-5 years old which resulted in an MOE = 180. If the residential risk estimates (dermal and oral) were updated to account for the increase in rate of the granular product, the resulting MOE = 120. The increase in rate, therefore, does not result in a risk of concern to the Agency; however, an updated assessment of bifenthrin aggregate risk may be required under registration review based upon the final determination for bifenthrin safety factors. Furthermore, an aggregate risk assessment may be needed to reflect changes in the dietary and water risk assessments. A new dietary risk assessment will be required after receiving crop field trial data or a registration request for a new use. It should include the residue levels reported in the most recent PDP database, %CT values reported in the most recent SLUA and changes to the dietary burden.

8.0 Occupational Exposure

Occupational exposure to bifenthrin is anticipated for adults who apply bifenthrin-containing products and from post-application exposure, or re-entry into previously treated areas. HED used the Biological and Economics Analysis Division (BEAD) Label Data System to identify all occupational uses of bifenthrin. Occupational bifenthrin use sites are many, including non-feed and food/feed uses. Examples of registered bifenthrin non-feed uses include outdoor premises: agricultural/farm, airports/landing fields, Christmas tree plantations, commercial and industrial lawns, forest trees, herbs, rights of way/fences/hedgerows, ornamental plants, and wide area treatments (public health, forest products) and indoor premises including: automobiles/taxis,

barns, warehouses, dairy/cheese processing plants, eating establishments, egg packing plants, greenhouses, and outdoor buildings. Examples of registered bifenthrin food/feed uses include: beans, herbs, root vegetables, tree nuts, stone fruits, bushberries, leafy green vegetables, brassica, peas, leaf petiole vegetables, orchard crops, and cucurbits/melons/squashes. Rates of application for occupational bifenthrin use vary from 0.1 to 0.2 lb ai/A for application by aircraft, ground, and chemigation equipment, 0.3 to 0.5 lbai/A for soil incorporation, 0.2 to 0.4 for dispersal of granular product with ground equipment, 0.005 lb ai/1000 ft^2 for crack and crevice and spot treatment applications, and 0.2 lb ai/A for spray and foam injection application.

A number of occupational assessments have been performed over the course of several years to address bifenthrin uses. Based upon review of the assessments identified, HED has determined that a majority of the use sites were not assessed per each individual site and instead by means of worst case estimates per crop grouping. For example, an occupational handler and post-application exposure/risk assessment for the bushberry crop subgroup was conducted in the document, "Bifenthrin - Occupational Exposure/Risk Assessment for the Proposed Use of Bifenthrin on Bushberries and Leaf Petiole Vegetables" (M Dow, D346755). The assessment which included the groups high- and low-bush blueberries can apply to all of the following: blackberry, blueberry, currant, dewberry, elderberry, gooseberry, huckleberry, loganberry, olallie berry, raspberry and youngberry.

HED has identified a few use sites which could not be accounted for by within crop group comparison alone. These include: canola and rape grown for seed, corn, cotton, the cucurbit crop grouping (melons, watermelon, squash, cucumber, gourds, and pumpkin) and strawberry use sites. Upon further review, the following occupational exposure/risk assessments were identified for these use sites:

- Canola and rape grown for seed: "Washington Section 18 Request (95WA0010) To Use Bifenthrin (Capture 2 EC Insecticide/ Miticide) To Control the Cabbage and Turnip Aphid on Canola and Rape Grown for Seed. B. Kitchens. D212599. March 15, 1995."
- Corn: "Non-Dietary Exposure Assessment for the Application of Capture 2 EC (Bifenthrin) to Seed Corn and Pop Corn. S. Knott. August 14, 1989."
- Cotton: "Handler Exposure Assessment for Bifenthrin Use on Cotton and Associated Risk. B. Backus. June 28, 1989."
- Cucurbit crop grouping: "Section 18 Request for the Use of Bifenthrin on Cucurbits to Control the Sweetpotato Whitefly in California. A. Lindsay. March 12, 1992."
- Strawberry: "Bifenthrin Exposure Assessment. L. Lewis. May 28, 1987."

Canola and rape grown for seed, cotton and strawberry were assessed at rates of 0.04 lb ai/ A, 1.0 lb ai/A, and 0.2 lb ai/ A, respectively, for aerial and ground applications. The corn and curcurbit crop grouping were assessed at a rate of 0.1 lb ai/A for aerial and ground applications.

While the identified occupational assessments account for the use site registrations, all were performed 15 years ago or later and, therefore, are not reflective of current policy or procedures and the most current occupational exposure data. Furthermore, no Section 3 assessment was identified for the curcurbit crop grouping use site and an occupational post-application assessment was not identified for any of the use sites in question. However, an update of the handler exposure assessment is not anticipated in registration review based on the following reasoning.

The currently registered rates of application and equipment identified for canola and rape grown for seed, corn, cotton, cucurbits and strawberry uses (i.e., 0.1 – 0.2 lb ai/ A applied by aircraft, ground or chemigation equipment, or 0.2 lb ai/ A applied by soil incorporated equipment) are consistent with recent bifenthrin crop grouping occupational handler assessments; beans, leafy green vegetables, and leaf petiole vegetables, to name a few. Despite the use sites not fitting within the recently assessed crop groupings, the use sites and crop groupings are identical in rate and application equipment and are, therefore, comparable. Based upon this comparison, all of the registered use sites in question are not of concern to the Agency and, therefore, an update of the handler exposure assessment is not anticipated in registration review. HED conducted a worst case post-application exposure assessment for the use sites in question by means of selecting the highest application rate and agricultural work activity transfer coefficient (TC) combination. The combination resulting in the greatest risk potential is an application rate of 0.1 lb ai/ A in corn and TC of 17,000 cm^2/hr, which is associated with de-tassling corn. The restricted entry interval estimate for this combination is an MOE = 110 on the day of application which tracks with the current, 12 hour, REI and, likewise, no update of the occupational post-application assessment is required.

9.0 Occupational Handler and Post-application Risk

Based upon review of all identified occupational use sites for bifenthrin and assessments for bifenthrin, HED has determined that most have been assessed adequately. As was the case for residential use of bifenthrin, a granular product was identified. The product is used in occupational settings (commercial/industrial lawns, golf course turf, and ornamental plants/turf) at a rate of 0.4 lb ai/A. Based on a comparison of previously assessed exposure scenarios for the registered granular rate (0.2 lb ai/A) and the 0.4 lb ai/A rate, the higher rate would not result in a risk of concern to the Agency for occupational handlers, nor does it impact the restricted entry interval (REI) for the applicable use sites. However, an occupational assessment of the granular product at the higher rate should be performed under registration review to capture the increase.

An updated occupational assessment may be required for any bifenthrin use site if new data are identified which impact exposure estimates, new points of departure, or revisions to exposure policies and procedures are made. Furthermore, based upon the final determination for bifenthrin safety factors, the occupational assessment of bifenthrin should be reviewed to ensure that exposure/risk estimates are health protective.

10.0 Public Health and Pesticide Epidemiology Data

In general, information from the Incident Data System (IDS) and the NIOSH SENSOR data base indicate a moderately large numbers of incidents have been reported involving bifenthrin. In general, both the IDS and NIOSH SENSOR queries for bifenthrin resulted in moderately large numbers of case reports. Although most of these incidents were of low severity, it seemed even low amounts of bifenthrin can cause adverse health effects such as dermal and respiratory tract irritation and neurological symptoms such as dizziness and altered sensations. Based on the number of incidents reported and effects noted in both databases, the evaluation of incidents data warrants further analysis in the preliminary risk assessment phase of registration review. More details regarding incidents of exposure are provided in a separate HED document (ref:

Bifenthrin: Review of Human Incidents, D370916, Feb. 23, 2010). Bifenthrin is not included in the Agricultural Health Study (AHS).

11.0 Tolerance Assessment and International Harmonization

Where possible, EPA encourages the harmonization of the US Tolerances and Maximum Residue Limits (MRLs) in key export markets. A table with the US tolerances, the Canada MRLs, Mexico MRLs and Codex MRLs for Bifenthrin in registered RACs is provided in Attachment 2. These tolerances and MRLs are based on the residue analysis of bifenthrin.

The current US tolerances are identical to the Codex MRLs for cattle meat, field corn grain, dried hop cones, pear, poultry fat, poultry meat byproducts, and poultry meat; therefore, these commodities are already harmonized. The US tolerances are higher than the Codex MRLs for cattle fat, cattle kidney, cattle liver, field corn stover, egg, milk fat, strawberry and potato.

Currently, Canada does not have MRLs established for the use of Bifenthrin. Mexico has established identical MRLs to the US tolerances for eight RACs. However, for Pea and Bean, the MRLs established by Mexico are higher than US tolerances while lower for Tomato and Potato. However, Mexico generally defaults to US or Codex tolerances/MRLs for its export purposes. The Agency will work to harmonize tolerances/MRLs, where possible, during registration review.

12.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.epa.gov/compliance/resources/policies/ej/exec_order_12898.pdf.

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by USDA under the CSFII, and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Whenever appropriate, non-dietary exposures based on home use of pesticide products, associated risks for adult applicators, and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

13.0 Cumulative

Bifenthrin is a member of the pyrethroid class of insecticides. This class also includes permethrin, cypermethrin, cyfluthrin, fluvalinate, deltamethrin, fenpropathrin, and lambda-

cyhalothrin, among others. EPA developed a draft science policy document on the proposed common mechanism of toxicity for naturally-occurring pyrethrins and synthetic pyrethroids (Proposed common mechanism grouping for the pyrethrins and pyrethroids, draft, May 19, 2009; http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809a62df). This document was supported by the FIFRA Scientific Advisory Panel (SAP) and EPA will finalize the policy document on the pyrethroid common mechanism of toxicity taking into account the SAP comments. Pesticides with a common mechanism of toxicity are subject to cumulative risk assessment under the FQPA. Research is on-going by EPA's Office of Research and Development (ORD) to make improvements to the SHEDS probabilistic exposure model which are important for the cumulative risk assessment. EPA ORD is also developing physiologically-based pharmacokinetic models for several pyrethroids. The status of both of these research modeling efforts will be reviewed by the FIFRA SAP in July, 2010. For information regarding EPA's efforts to evaluate the risk to pyrethroids, see the following website http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

14.0 Human Studies

Past bifenthrin risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED), the Agricultural Reentry Task Force (ARTF) Database, and the Outdoor Residential Exposure Task Force (ORETF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

15.0 Data Requirements

Toxicology

870.3465 90-Day/28-Day Inhalation Study

This requirement is based on the potential inhalation exposure to workers from all registered spray application uses. This study is required if there is the likelihood of significant repeated inhalation exposure to the pesticide as a gas, vapor or aerosol. The exposure time may be reduced from 90 days to 28 days pending exposure patterns, plateauing of effects and considering overall toxicity potential of bifenthrin. The HIARC (Feb. 19, 2003) identified this study as a data gap for bifenthrin and recommended a 90-day inhalation toxicity study be conducted. In the April 6, 2006 risk assessment, a waiver was given to the study based upon criterion IV of the HED's inhalation data waiver criteria check list, which includes the requirement that bifenthrin be assigned to Category IV for acute toxicity. Upon further evaluation, the acute toxicity study requirement has not actually been fulfilled due to the reported inability for an acceptable atmosphere of the test substance to be generated. Therefore, the sub-chronic toxicity study does not qualify for a waiver and is still considered a data gap.

870.7800 Immunotoxicity

There is a new requirement for a series 870.7800 immunotoxicity study. Immunotoxicity study is required as a part of the new data requirements in the 40 CFR Part 158 for conventional pesticide registration. Because the immune system is highly complex, studies not specifically conducted to assess immunotoxic endpoints are inadequate to characterize a pesticide's potential immunotoxicity. While data from hematology, lymphoid organ weights, and histopathology in routine chronic or sub-chronic toxicity studies may offer useful information on potential immunotoxic effects, these endpoints alone are insufficient to predict immunotoxicity. In the absence of required studies, EPA may use a database uncertainty factor of up to 10X. Once all data have been received and reviewed, the Bifenthrin Registration Review Team recommends that the points of departure and uncertainty factors used for risk assessment purposes be re-examined and a new risk assessment done, if necessary.

The uncertainty factors for bifenthrin are 10X for intra-species and 10X for inter-species. Based on the Agency's review of existing pyrethroid data, EPA has come to the conclusion that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. The Agency is investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms.

Residue Chemistry

860.1500 Crop Field Trials

- For the herb subgroup19A, field trials using an appropriate and practical pre-shipment interval are requested.
- The 25% EC formulation is used on artichoke, caneberry subgroup 13-07A, and hops. Crop field trials are not available; therefore, these must be performed or alternatively the use of the 25% EC formulation for these RACs must be eliminated from the label(s).
- No crop field trials are available for cotton gin byproducts. These should be submitted to evaluate residue levels and if necessary an evaluation of the dietary burden to livestock will be made.
- Three field trials are requested for grapes in order to fulfill geographic representation requirements.

860.1340 Residue Analytical Method

- When the revised version of the method P-2763 is submitted to the agency it will be evaluated to establish if it meets the requirements for tolerance enforcement in walnuts.

16.0 References

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Bifenthrin. Residue and Product Chemistry Considerations for the Tolerance Reassessment Eligibility Decision (TRED), Sarah J. Levy, DP Barcode: 283808, Aug 21, 2002

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Bifenthrin (Chemical No. 128825). PP#6E7125, PP#6E7126, PP#6E7127, PP#6E7128; Section 3 Registration for Application of Bifenthrin to Mayhaw, Root Vegetables, (Except Sugar Beets, Crop Subgroup 1B), Peanut, Pistachio, Soybean, and Fruiting Vegetables (Crop Group 8). Summary of Residue Chemistry Data, William Wassell, DP Barcodes: 335693, 335688, 335696, 335695, MRIDs: 46098701, 46960801, 46961101-46961103, 46960401-46960404, Jul 25, 2007

Bifenthrin (128825). Section 3 Registration Request for Application of Bifenthrin to Bushberry (Crop Subgroup 13B), Juneberry, Lingonberry, Salal, Aronia Berry, Lowbush Blueberry, Buffalo Currant, Chilean Guava, European Barberry, Highbush Cranberry, Honeysuckle, Jostaberry, Native Current, Sea Buckthorn, and Leaf Petioles (Crop Subgroup 4B) and FMC Corporation's Field Trial Data on Head Lettuce. Summary of Analytical Chemistry and Residue Data, William D. Wassell, DP Barcodes: 342661, MRIDs: 47144501, 47144502, and 47144503, Apr 01, 2008

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Bifenthrin: Review of Human Incidents, K. Oo, J. Cordova, S. Recore, Feb. 25, 2010, D370916

16.0 Attachments

Attachment 1: Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100	90-Day oral toxicity (rat)	00141199 (1984) Acceptable/guideline M: 0, 0.88, 3.8, 7.5, 15 mg/kg/day F: 0, 1.04, 4.3, 8.5, 17.2 mg/kg/day	NOAEL=M/F: 3.8/4.3 mg/kg/day LOAEL=M/F: 7.5/8.5 mg/kg/day based on increased incidence of tremors.
870.3150	90-Day oral toxicity (dog)	00141200 (1984) Acceptable/guideline 0, 2.21, 4.42, 8.84, 17.7 mg/kg/day	NOAEL =M/F: 2.21 mg/kg/day LOAEL = M/F: 4.42 mg/kg/day based on based on increased incidence of tremors.
870.3200	21/28-Day dermal toxicity (rat)	45280501 (2000) Acceptable/guideline 0, 23, 47, 93, 932 mg/kg/day	NOAEL = 47 LOAEL = 93 mg/kg/day based on staggered gait and exaggerated hindlimb flexion.
870.3200	21/28-Day dermal toxicity (rabbit)	00141198 (1984) Acceptable/guideline 0, 22, 44, 88 442 mg/kg/day	NOAEL = 88 mg/kg/day LOAEL = 442 mg/kg/day based on loss of muscle coordination and increased incidence of tremors.
870.3700a	Prenatal developmental in (rat, gavage)	00154482 (1983) Acceptable/non-guideline 0, 0.44, 0.88, 1.77, 2.2 mg/kg/day	**Maternal** NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. **Developmental** NOAEL and LOAEL were not established (fetuses were not examined).
870.3700a	Prenatal developmental in (rat, gavage)	00141201 (1984) Acceptable/guideline 0, 0.44, 0.88, 1.77 mg/kg/day	**Maternal** NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors. **Developmental** NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on increased fetal and litter incidence of hydroureter without nephrosis.

Attachment 1: Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3700a	Prenatal developmental in (rat, diet)	45352301 (2001) Acceptable/guideline 0, 2.4, 4.8, 7.1, 15.5 mg/kg/day	**Maternal** NOAEL = 7.1 mg/kg/day LOAEL = 15.5 mg/kg/day based on clinical signs and decreased food consumption, body weight gains, and body weight gains (adjusted for gravid uterine weight). **Developmental** NOAEL = 15.5 mg/kg/day LOAEL was not established.
870.3700b	Prenatal developmental in (rabbit, gavage)	00145997 (1984) Acceptable/guideline 0, 2.36, 3.5, 7 mg/kg/day	**Maternal** NOAEL = 2.36 mg/kg/day, LOAEL = 3.5 mg/kg/day based on treatment-related head and forelimb twitching. **Developmental** NOAEL =7 mg/kg/day, LOAEL was not established.
870.3800	Reproduction and fertility effects (rat)	00157225 (1986) Acceptable/guideline 0, 1.5, 3.0, 5.0 mg/kg/day	**Parental/Systemic** NOAEL = M/F: 5.0/3.0 mg/kg/day, LOAEL was not established in males. In females, LOAEL= 5.0 mg/kg/day based on tremors and decreased body weights. **Reproductive/ Offspring** NOAEL = 5.0 mg/kg/day, **Reproductive/ Offspring** LOAEL was not established.
870.4100b	Chronic toxicity (dog)	00163065 (1985) Acceptable/guideline 0, 0.66, 1.3, 2.7, 4.4 mg/kg/day	NOAEL = 1.3 mg/kg/day, LOAEL= 2.7 mg/kg/day based on increased incidence of tremors.
870.4300	Chronic/ Carcinogenicity (rat)	00157226 (1986) Acceptable/guideline M: 0, 0.6, 2.3, 4.7, 9.7 mg/kg/day F: 0, 0.7, 3.0, 6.1, 12.7 mg/kg/day	NOAEL = M/F: 4.7/3.0 mg/kg/day, LOAEL =M/F: 9.7/6.1 mg/kg/day based on increased incidence of tremors. **No conclusive evidence of carcinogenicity**

Attachment 1: Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.4300	Chronic/ Carcinogenicity (mouse)	00157227 (1986) Acceptable/guideline M: 0, 6.7, 25.6, 65.4, 81.3 mg/kg/day F: 0, 8.8, 32.7, 82.2, 97.2 mg/kg/day	NOAEL =M/F: 6.7/8.8 mg/kg/day, LOAEL = M/F: 25.6/32.7 mg/kg/day based on based on increased incidence of tremors. **Carcinogenic** potential was evidenced by a dose-related increase in the incidence of leiomyosarcomas in the urinary bladder, a significant dose-related trend for combined hepatocellular adenomas and carcinomas in males, and a significantly higher incidence of combined lung adenomas and carcinomas in females.
870.6200a	Acute neurotoxicity (rat, gavage)	44862102(1998) Acceptable/Guideline 0, 9.4, 32.8, 70.3 mg/kg/day	NOAEL = 32.8 mg/kg/day, LOAEL=70.3 mg/kg/day based on clinical signs of toxicity, FOB findings, altered motor activity, and mortality (females only).
870.6200b	Subchronic neurotoxicity screening battery (rat)	44862103 (1998) Acceptable/Guideline M: 0, 2.7, 5.6, 11.1 mg/kg/day F: 0, 3.5, 6.7, 13.7 mg/kg/day	NOAEL= M/F: 2.7/3.5 mg/kg/day, LOAEL= M/F: 5.6/6.7 mg/kg/day based on neuromuscular findings (tremors, changes in grip strength and landing foot-splay).

Attachment 1: Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.6300	Developmental Neurotoxicity (rat)	46750501 (2006) Acceptable/non-guideline 0, 3.6, 7.2 and 9.0 mg/kg/day (gestation) 0, 8.3, 16.2 and 20.7 mg/kg/day (lactation)	**Maternal** NOAEL = 3.6 mg/kg/day during gestation and 8.3 mg/kg/day during lactation, LOAEL = 7.2 mg/kg/day during gestation and 16.2 mg/kg/day during lactation based on clinical signs of neurotoxicity (tremors, clonic convulsions, and increased grooming counts). **Developmental** NOAEL =3.6 mg/kg/day during gestation and 8.3 mg/kg/day during lactation. **Developmental** LOAEL = 7.2 mg/kg/day during gestation and 16.2 mg/kg/day during lactation based on clinical signs of neurotoxicity (increased grooming counts).

Attachment 2. Bifenthrin US and International Tolerances and Maximum Residue Limits				
US[1]		**Canada**	**Mexico[2]**	**Codex[3]**
Residue Definition:				
40 CFR 180.442 Bifenthrin ((2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate)		None	Bifenthrin	Bifenthrin (fat-soluble).
Commodity Tolerance (ppm) /Maximum Residue Limit (mg/kg)				
Commodity	US	Canada	Mexico[2]	Codex
Almond, hulls	2.0	None		
Artichoke, globe	1.0			
Banana[1]	0.1			
Beet, garden, roots	0.45			
Beet, garden, tops	15			
Brassica, head and stem, subgroup 5A, except cabbage	0.6		0.6 broccoli 0.6 Brussels sprouts 0.6 cauliflower	
Brassica, leafy greens, subgroup 5B	3.5			
Bushberry subgroup 13-07B	1.8			
Cabbage	4.0		4	
Caneberry subgroup 13A	1.0			
Cattle, fat	1.0			0.5
Cattle, meat byproducts	0.10			0.05 (*) kidney; liver
Cattle, meat	0.5			0.5
Coriander, dried leaves	25			
Coriander, leaves	6.0			
Coriander, seed	5.0			
Corn, field, forage	3.0			
Corn, field, grain	0.05			0.05 (*)
Corn, field, stover	5.0			0.2 (dry)
Corn, pop, grain	0.05			
Corn, pop, stover	5.0			
Corn, sweet, forage	3.0			
Corn, sweet, kernel plus cob with husk removed	0.05			
Corn, sweet, stover	5.0			
Cotton, undelinted seed	0.5		0.5	
Eggplant	0.05			
Egg	0.05			0.01 (*)
Fruit, citrus, group 10	0.05			
Goat, fat	1.0			

Attachment 2. Bifenthrin US and International Tolerances and Maximum Residue Limits				
US[1]		**Canada**	**Mexico[2]**	**Codex[3]**
Goat, meat byproducts	0.10			
Goat, meat	0.5			
Grain, aspirated fractions	70			
Grape	0.2			
Groundcherry	0.5			
Herb subgroup 19A	0.05			
Hog, fat	1.0			
Hog, meat byproducts	0.10			
Hog, meat	0.5			
Hop, dried cones	10.0			10
Horse, fat	1.0			
Horse, meat byproducts	0.10			
Horse, meat	0.5			
Leafy petioles subgroup 4B	3.0			
Lettuce, head	3.0		3	
Mayhaw	1.4			
Milk, fat (reflecting 0.1 ppm in whole milk)	1.0			0.05 (*)
Nut, tree, group 14	0.05			
Okra	0.50			
Pea and bean, dried shelled, expect soybean, subgroup 6C	0.15		0.5 pea 0.5 bean (no indication of dried or succulent)	
Pea and bean, succulent shelled, subgroup 6B	0.05			
Peanut	0.05			
Pear	0.5			0.5
Pepino	0.5			
Pepper, bell	0.5			
Pepper, nonbell	0.5		0.5	
Pistachio	0.05			
Poultry, fat	0.05			0.05 (*)
Poultry, meat byproducts	0.05			0.05 (*)
Poultry, meat	0.05			0.05 (*)
Radish, tops	4.5			
Rapeseed, seed	0.05			
Sheep, fat	1.0			
Sheep, meat byproducts	0.1			
Sheep, meat	0.5			
Soybean, hulls	0.50			

Attachment 2. Bifenthrin US and International Tolerances and Maximum Residue Limits				
US[1]		**Canada**	**Mexico[2]**	**Codex[3]**
Soybean, refined oil	0.30			
Soybean, seed	0.2			
Spinach	0.2			
Strawberry	3.0		0.5	1
Tomato	0.15		0.15	
Turnip, greens	3.5			
Vegetable, cucurbit, group 9	0.4			
Vegetable, legume, edible podded, subgroup 6A	0.6			
Vegetable, root, subgroup 1B except sugar beet and garden beet	0.10		0.05 potato	0.05 potato
Vegetable, tuberous and corm, subgroup 1C	0.05			
Tolerances for two additional commodities are included in the CFR but their revocation date is 12/31/09. These are:				
Orchardgrass, forage	2.5			
Orchardgrass, hay	4.5			
Non-US MRLs with no US Equivalent				
Barley	-			0.05 (*)
Barley straw and fodder, dry	-			0.5
Grapefruit	-			0.05 (*)
Lemon	-			0.05 (*)
Orange, sweet	-			0.05 (*)
Wheat	-			0.5 (*) Po
Wheat bran, unprocessed	-			2 PoP
Wheat flour	-			0.2 PoP
Wheat straw and fodder, dry	-			0.5
Wheat wholemeal	-			0.5 PoP

[1]There are no U.S. registrations as of April 30, 2003.
[2] Information for Mexico is dated. Mexico adopts US tolerances or Codex MRLs for its trade purposes.
[3] * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat.

Attachment 3: Data Needs for Bifenthrin

Guideline Number: 870.3465 **Study Title: 90-Day/28-Day Inhalation Toxicity**
Rationale for Requiring the Data
Instead of conducting the inhalation study for 90-days, the Agency only needs a 28-day inhalation study because only short- and intermediate-term (but not long-term) exposure to workers is expected based on bifenthrin's use pattern. A longer-term inhalation study is required in situations in which a specific concern exists for increased hazard related to exposure via the inhalation route. The 28-day inhalation toxicity study evaluates the potential hazard of a pesticide chemical following repeated inhalation exposures. This study is critical for pesticides with use patterns in which there is potential for repeated human exposures (e.g., professional applicators, green house use, etc.). The study design simulates the route of human exposure (inhalation). In this study, animals are exposed (nose/whole body) to aerosol concentrations of the test material for 6 hours/day, 5 days/week for 28 days. A detailed toxicological examination including the histopathology of the respiratory system is conducted. This route-specific study would provide data for hazard characterization, dose response assessment, and a dose and endpoint for assessing potential risks via the inhalation route.
Practical Utility of the Data
How will the data be used? This study will identify hazard (i.e., provide a dose and endpoint) following repeated inhalation exposures. The results will be used in risk assessments as appropriate. **How could the data impact the Agency's decision-making?** A sub-chronic inhalation study provides critical scientific information needed to characterize potential hazard to the human respiratory system from pesticide exposure. In the case of bifenthrin, there is no acceptable inhalation study available. A 28-day repeated exposure study that follows the Test Guidelines (870.3465) will characterize hazard and provide data for a more refined inhalation risk assessment. Exposure time may be reduced 28 days pending exposure patterns, plateauing of effects and considering the overall toxicity potential of bifenthrin. This requirement is pending resolution of inhalation exposure for existing and possible future uses.

Guideline Number: 870.7800 **Study Title: Immunotoxicity**
Rationale for Requiring the Data
This is a new data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses). The Immunotoxicity Test Guideline (OPPTS 870.7800) prescribes functional immunotoxicity testing and is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Immunosuppression is a deficit in the ability of the immune system to respond to a challenge of bacterial or viral infections such as tuberculosis (TB), Severe Acquired Respiratory Syndrome (SARS), or neoplasia. Because the immune system is highly complex, studies assessing functional immunotoxic endpoints are helpful in fully characterizing a pesticide's potential immunotoxicity. These data will be used in combination with data from hematology, lymphoid organ weights, and histopathology in routine chronic or sub-chronic toxicity studies to characterize potential immunotoxic effects.
Practical Utility of the Data
How will the data be used?

These animal studies can be used to select endpoints and doses for use in risk assessment of all exposure scenarios and are considered a primary data source for reliable reference dose calculation. For example, animal studies have demonstrated that immunotoxicity in rodents is one of the more sensitive manifestations of TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin) among developmental, reproductive, and endocrinologic toxicities. Additionally, the EPA has established an oral reference dose (RfD) for tributyltin oxide (TBTO) based on observed immunotoxicity in animal studies (IRIS, 1997).

How could the data impact the Agency's future decision-making?

If the immunotoxicity study shows that the test material poses either a greater or a diminished risk than that given in the interim decision's conclusion, the risk assessments for the test material may need to be revised to reflect the magnitude of potential risk derived from the new data.

If the Agency does not have this data, a 10X database uncertainty factor may be applied for conducting a risk assessment from the available studies.

Guideline Number: 860.1500
Study Title: Crop field trials – (herb subgroup19A, artichoke, caneberry subgroup, hops, cotton gin byproducts, and grapes)

Rationale for Requiring the Data

Field trials are required for each commodity/commodity group according to guidelines that take into account where the crop is grown and how much of the crop is grown. Field trials are required for each type of formulation because the formulation can have significant effect on the magnitude of the pesticide residue left on the crop. Residue trials also need to represent the maximum application rate on the label and have a geographic distribution representative of the commodity/commodity group. Some of the best ways to gather such information is to compare residues derived from different types of formulations and side-by-side trials.

Practical Utility of the Data for the Herb subgroup19A

Crop field trials must be conducted to reflect the use pattern. The proposed 70-day PHI for the shipment of container-grown herbs grown in fire ant quarantine areas is not enforceable since the containers will likely be outside the grower's control at the proposed PHI. The 70-day PHI should be amended to reflect a realistic pre-shipment interval. Crop field trial data that depicts the amended use should be submitted. The numbers of field trials requested for the herb subgroup 19A are: three for basil and three for chives.

How will the data be used?

These data will allow EPA to set enforceable tolerance levels that farmers and producers will be able to rely upon for trade and commerce. The farmers and producers depend upon EPA to set appropriate tolerance levels in conjunction with label directions that would prevent legal uses from producing over-tolerance residues, and thereby resulting in crop seizure. Once the tolerance levels are determined, dietary risk will be assessed.

How could the data impact the Agency's future decision-making?
These data could alter current tolerances. If the tolerances change, this data may impact the tolerances that are currently established and would also need to be included in the dietary risks assessment. If the dietary risk is increased, then additional mitigation may be needed to address potential risks of concern and (if necessary) an aggregate risk assessment.

Practical Utility of the Data for Artichoke, Caneberry subgroup 13-07A, and Hops

Crop field trials are required for each type of formulation and must be conducted in areas reflecting the geographic distribution. The trials on these commodities were performed with the 10% WP formulation; therefore, trials with the EC formulation are required. The numbers of field trials required for these RAC are: two or three for globe artichoke, five for the caneberry subgroup, and three for hops. Alternatively, use directions for these commodities may be removed from the labels of the EC formulation.

How will the data be used?
Once the data from the requested field trials are received, the Agency will compare the information from the trials. Revised tolerances may be needed for artichoke, caneberry subgroup 13-07A and Hops. Farmers rely on the Agency to set adequate and appropriate tolerances in conjunction with label directions. Farmers understand that if they rely on label directions and follow those directions, their crop will be under-tolerance and can therefore be sold in interstate commerce thereby preventing legal uses from producing over-tolerance residues resulting in crop seizure.

How could the data impact the Agency's future decision-making?
These data could alter current tolerances. As mentioned previously, when new tolerances are established, the dietary risk will be assessed. Therefore, these data will allow the Agency to determine a more accurate dietary exposure analysis and (if necessary) an aggregate risk assessment.

Practical Utility of the Data for Cotton Gin Byproducts

Crop field trial data is required for each RAC. Based on the use of bifenthrin in/on cotton a tolerance for it presence of cotton gin byproducts is required. Currently, no crop field trial data are available for the residues of bifenthrin in cotton gin byproducts at the maximum seasonal application rate. Three field trials reflecting stripper harvest are required to establish a tolerance for cotton gin byproducts. These data must be submitted in order to establish a tolerance based on the residues on/in cotton gin byproducts.

How will the data be used?

Once the data from the requested field trials are received, the Agency will establish a tolerance for cotton gin byproducts. Farmers rely on the Agency to set adequate and appropriate tolerances in conjunction with label directions. Farmers understand that if they rely on label directions and follow those directions, their crop will be under-tolerance and can therefore be sold in interstate commerce thereby preventing legal uses from producing over-tolerance residues resulting in crop seizure.

How could the data impact the Agency's future decision-making?

These data will allow the agency to establish a tolerance for the cotton gin byproducts. When a new tolerance is establish, the livestock dietary burden and dietary risk will be assessed. Therefore, these data will allow the Agency to determine a more accurate dietary exposure analysis and (if necessary) an aggregate risk assessment.

Practical Utility of the Data for Grapes

Crop field trials must be conducted in areas reflecting the geographic distribution. Based on the 2002 TRED, three additional trials are required to fulfill geographic representation requirements, two in region 10 and one in region 11. These trials should be performed with EC formulation and the established use pattern.

How will the data be used?

Once the data from the requested field trials are received, the Agency will compare the information. Revised tolerances may be needed for grapes. Farmers rely on the Agency to set adequate and appropriate tolerances in conjunction with label directions. Farmers understand that if they rely on label directions and follow those directions, their crop will be under-tolerance and can therefore be sold in interstate commerce thereby preventing legal uses from producing over-tolerance residues resulting in crop seizure.

How could the data impact the Agency's future decision-making?
These data could alter current tolerances. As mentioned previously, when new tolerances are established, the dietary risk will be assessed. Therefore, these data will allow the Agency to determine a more accurate dietary exposure analysis and (if necessary) an aggregate risk assessment.